Statement of Work

I. Title: Exposure Assessment Support, Consumer Exposure Model (CEM) updates and Fate Testing Guidelines
Contractor Name: ICF
Contract #: EP-W-12-010
WA #: 4-53

II. Work Assignment Manager (WAM):

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III. Background:

Consumer exposure model (CEM) finalization

Background for Consumer Exposure Needs of OPPT
The Consumer Exposure Model (CEM) has been a separate module under the E-FAST/NCEM2 Model but with the prioritization of the EPA on toxics and consumer products is encompassing more pathways and release parameters to warrant a stand-alone model. Multiple consumer exposure models have been evaluated and are considered for their unique properties for inclusion within the CEM suite of consumer exposure pathways. All models will include activities patterns including the populations exposed, activities patterns of the direct user and indirect exposed individual.

The set of tools needed to provide exposure estimates on screening and complex levels will be evaluated and incorporated into the CEM. Articles have multiple ways to shed chemicals both chemically and physically. Once removed from the article, adsorption or absorption, deposition and then local and global transport can occur as various fates, transport and meteorological conditions apply. CEM will also contain information that is product specific and activity patterns that will provide default scenarios that are transparently described as well as the flexibility for user-created scenarios.

Consideration of multiple exposure pathways (oral, inhalation, and dermal) from direct contact with products and articles as well as proximity-related indirect exposures from products and articles will be covered by the updated CEM. This flexibility is congruent with OPPT's needs to assess a wide range of chemical substances used in products, including articles, in a wide range of environments.

Background for Exposure Assessment Needs of OPPT

Another area to be considered part of this work assignment is that of exposure assessment. OPPT assesses indoor exposures to consumers, general population exposures from the ambient environment, and ecological exposures for aquatic and terrestrial organisms. Many past efforts to characterize exposures have focused on Volatile Organic Compounds (VOCs). However, Semi-Volatile Organic Compounds (SVOCs) now comprise the majority of chemicals which OPPT is assessing. SVOCs are being found at concerning rates. Almost any time a researcher turns their sophisticated tools and knowledge towards any commonplace item such as gymnastics pits, play tents, shower curtains, flooring, carpets, etc., they find a multitude of SVOCs, including phthalates, perfluorinated compounds, flame retardants, etc. Studies from remote locations and environmental species are also showing concentrations of chemicals that were previously not thought to be a concern for global transport based on their physical chemical properties, i.e., lack of volatility. SVOCs have a complex pathway from the articles that they are added to, such as upholstered furniture, building insulation foams, paints, etc., to the environmental media such as surface water or soil.

Background for Proof of Concept Testing

Polymers are endemic in the world today as they have been for the last 50 years or so. As the technologies change and more uses of polymers have been explored and introduced widely into the marketplace, so, too, has the number of additive chemicals been found in various media and environments. Water bodies make up over 2/3 of the earth's surface; therefore, it should be no surprise that they end up being the wayward polymers' 'graveyard'. These are polymeric materials with their additives that are dumped into the ocean, that blow off the paddle boat into the river, that are washed from soils containing bio solids made from contaminated sludge from sewage treatment plants. Data are lacking to understand how materials that are exposed to the rock-reducing elements, such as wind, rain and tides, allow the chemicals added in polymers to become released into those waters.

A laboratory methods guideline is needed to understand and compare releases from polymeric materials under various conditions in order to understand how better to design polymers and polymer additives so they do not pollute our waters. Under this work assignment, a laboratory guideline will be developed to provide a basis for data collection of polymer additive release into water. This guideline will be used under the Pre-Manufacturing (PMN) Program for inclusion in the testing regimes for chemicals that are expected to be added to polymers that are marketed and used widely. Over time it has been shown again and again that chemicals added into plastics such as DEHP, DIDP, brominated flame retardants, perfluorinated compounds, will eventually find their way into various environmental media. The expectation with this method guideline, a predictive model will be developed based on several chemicals that will allow the Agency to

predict what chemicals fit into this category, thereby allowing an option for a full hazard data set to be collected.

Background for Exposure Support Needs of OPPT

Another area to be considered part of this work assignment is that of exposure support activities. These activities comprise any activity related to compilation, analysis, or review of data that is not explicitly used in an exposure assessment and is instead used as a stand-alone deliverable. Examples of exposure support activities include generation or review of exposure testing protocols to support testing rules, refinement of exposure factors or activity patterns, consideration of environmental and biological monitoring data to inform which categories of chemicals and which physical-chemical properties inform where chemicals are more or less likely to be present within given media.

IV. Description and Tasks:

Task #1: Work Plan

The contractor shall submit a work plan and quality assurance quality control plan (QAPP) describing the contractor's approach and plan in accomplishing the tasks. The contractor shall also provide a dollar estimate along with an estimate of the hours by task and sub-task within 20 calendar days of receipt of this work assignment. Within 7 calendar days after receipt of the work assignment, the contractor shall contact the WAM to discuss any issues, questions and possible approaches. Regular calls, for example on a weekly or biweekly basis, after approval of the work plan will help with reviewing progress of this WA.

Task #2: Finalize Peer Review ready draft of Consumer Exposure Model

The contractor provided a draft mock-up of the AMEM model in an Excel spreadsheet format under Work Assignment 0-05. Much work was accomplished under WA 1-13 including the assimilation of the SVOC and AMEM capabilities into an ACCESS version of the CEM. An example consumer product use and user's activity patterns have been included to provide EPA with an initial product for review and testing the look and feel. EPA gathered information on available equations and default parameters to estimate exposures from the use of consumer products from approximately 10 other similar screening level deterministic models such as ECETOC and CONSEXPO using a different contract vehicle. This information has been incorporated into the Access version of CEM under WA 2-25. Information on defaults for consumer exposure scenarios has also been incorporated into CEM under WA 2-25. A beta testing version of CEM was delivered at the end of WA 2-25.

The beta testing period lasted for the month of August 2015 to October 2015 and feedback from several individuals was received. The contractor reviewed and incorporated feedback from beta testing in preparation of a Peer Review Ready draft of the Consumer Exposure Model and User's Guide by December 31, 2015. A letter peer review will be initiated and feedback is expected in 2016. After peer review feedback is obtained, the contractor shall review and incorporate feedback from peer review in developing a final version of the Consumer Exposure Model and

Users Guide by the end of the calendar year, December 31, 2016. If the peer review is not complete by then, this may extend to the end of the option year, March 31, 2017. The contractor shall initiate changes to the Consumer Exposure Model after receipt of Technical Direction from EPA. EPA will consider all suggested changes from beta testing and peer review. However, only a subset of these changes will be implemented. For suggestions that are not acted on, the contractor shall prepare a response to comments. Addition of one to two additional models and refinement of a subset of other models or estimation approaches within CEM is a likely outcome of this Task.

Task #3: Provide Targeted Support for Exposure Assessments

The contractor shall use guidelines developed in the QAPP and available data sources provided by EPA to develop exposure assessment or exposure assessment support materials. An example of an entire exposure assessment is the estimation of non-steady state estimates of multi-zone indoor concentrations following application of Spray Polyurethane Foam as conducted in WA 2-25. An example of exposure support materials is the estimates of nearby soil and water concentrations via AERMOD modeling from point sources.

The contractor shall assume that exposure assessments and exposure assessment support activities will be undertaken for work plan chemical assessments. The following website has information on ongoing TSCA work plan chemical assessments.
http://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-tsca-work-plan-chemicals

The following website has all TSCA work plan chemicals.

http://www.epa.gov/sites/production/files/2015-01/documents/tsca_work_plan_chemicals_2014_update-final.pdf

It is anticipated that only one full exposure assessment activity, covering most aspects of developing, updating, and documenting information needed for an exposure assessment is needed.

The contractor shall support seven exposure assessment support activities. These activities may include one or more of the following for a given chemical:

- Consumer exposure modeling
- General Population exposure modeling (AERMOD, surface water)
- Compilation or summarization of available monitoring data
- Interpretation of product testing information
- Compilation of EndNote file and associated references
- Formatting of exposure assessment files including references, equations, citations, and tables.

Exposure pathways to be included in upcoming assessments may include:

- dust ingestion,
- mouthing of products,

- soil ingestion,
- fish ingestion,
- drinking water ingestion,
- inhalation of suspended particles ambient air and indoor air,
- inhalation of vapor ambient air and indoor air,
- inhalation following use of consumer products
- dermal exposure during use of consumer products,
- dermal exposure from contact with dust or object surfaces,
- inhalation of vapor from volatilized treated water

Not all exposure pathways will be included for all work plan chemical assessments. The contractor shall work closely with EPA to finalize central tendency and high-end doses for each chemical and exposure pathway of interest. The contractor shall also provide recommendations for aggregating exposure pathways for a given chemical to derive an overall central tendency and high-end estimate dose for the chemical. Included in this consideration will be who is being exposed (near-facility general population), likelihood of co-occurrence of the pathways. This may be addressed qualitatively or quantitatively depending on the information available.

Task #4: Finalize Proof of Concept Test Method for Migration of Flame Retardants and Phthalates from Plastics

The contractor shall work with EPA to develop standard test method that will be used by industry to provide key data on the migration of their chemicals from plastics into environmental media. Many existing chemicals of current regulatory interest and new chemicals in the PMN process are used as additives in polymeric materials. Standard assumptions that polymer additives are not released or are released very slowly from the polymer have been shown to be less than accurate in many cases. Flame retardants, PFCs, photolysis inhibitors, plasticizers, etc. have been shown to migrate out of the polymer matrix and enter various media including air and dust, fresh and sea water, soil and sludge/bio solids. The mechanisms of additive release from polymers and rates of migration out of the polymer matrix are poorly understood, and there are no standard testing guidelines that can be used to measure the amount or rate of release for most environments. There are both physical and chemical mechanisms that will cause additive chemical to be released. For example the abrasion of polymer surfaces, photolytic aging and surface changes, mechanical breakdown of the polymer, biological or abiotic degradation of the polymer, etc. will release additive chemicals into media of potential exposure concern.

Under WA 1-13, WA-25, and WA 3-33 the contractor subcontracted this work to Robert C. Hale, Virginia Institute of Marine Science. An initial draft testing plan and protocol was submitted March 4, 2014. A QAPP was approved in December of 2014. This QAPP was revised and subsequently approved in January of 2016. Preliminary proof of concept samples were collected and analyzed in the last option year. The final data and report summarizing project activities is expected early in the option year.

Task #5: Develop Front-End Graphical User Interface for Simulation Model to characterize emissions and exposures from SPF and other materials with variable Short and Long-Term Emission profiles

EPA, in coordination with ICF, recently completed a paper for an ASTM symposium that documented modeling approach for estimating emissions and exposures to Spray Polyurethane Foam. The modeling combined code from existing EPA models, IAQX and I-SVOC, as well as code specifically for SPF. The contractor shall incorporate existing code and write new code into a graphical user interface (GUI). Reusable code from IAQX include algorithms for application-phase emulation, multi-zone air flow, and gas-phase chemical reactions. Reusable code from I-SVOC includes the modified state-space (MSS) representation of diffusional sources an dinks, airborne particles, and settled dust. New code includes information on seasonal variations in temperature and temperature-dependent variability for model input parameters for material-air partition coefficient (K) and Diffusion coefficient (D).

Develop a simulation program and User's Guide to implement OPPT's SPF model. The program will play a dual role: (1) as a special-purpose simulation program for SPF emissions; (2) as a general-purpose simulation program for SVOCs in buildings with multiple zones. While the majority of code can be reused, remaining code is associated with the user interface. The contractor shall use Lazarus Integrated Development Environment, an open source platform that is compatible with the existing IAQX and I-SVOC code written in Delphi. This task is specific to model development, integration, and associated Quality Control and Quality Assurance. It does not cover development of any technical manual, user's guide, or development of text associated with help screens to assist model users. This work may be undertaken in the future.

Task #6: Provide targeted Exposure Support (non-Assessment)

Exposure support activities not directly incorporated into an Exposure Assessment can be generally grouped into activities that focus on exposure-related testing and information gathering (A), refining exposure factors or generic activity patterns (B), or compiling databases that can be used as a reference for more in-depth work in support of an exposure assessment such as screening-level database with monitoring data (C). The contractor shall provide support across all three of these areas in a given option year, but only one of the three will have a focus for more robust work in a given year.

A) Collection of measured data in support of exposure assessment is important. OPPT can request information be generated to inform exposure assessments in its assessments. Unfortunately, standardized exposure protocols are lacking. OPPT has developed a draft set of exposure testing protocols, focused on indoor environment exposures and referencing existing protocols. These have undergone some revisions with feedback from other government Agencies. The contractor shall review and provide recommendations to improve the clarity, scope, and applicability of these protocols. While there are seven protocols, the total number of pages is approximately 25 and EPA does not expect the overall length and scope of the description of these protocols to change substantially. The goal is to introduce the type of testing, provide a non-prescriptive protocol allowing for flexibility, and provide references to existing protocols, with special emphasis on any

emerging testing methods developed since September 2015 when version 1 of the protocols was released. This information could be used in support of testing rules under Section 4, 5, or 8 of TSCA.

B) The Exposure Factors Handbook provides Agency recommended values for Age specific exposure factors and activity patterns. Certain refinements of targeted exposure factors or activity patterns may useful as stand-alone projects to later support exposure assessments. The contractor shall provide support to finalize one report summarizing any one of the following exposure factors and/or activity patterns. Examples include documentation and defining generic activity pattern profiles for use in models, refining existing dust and soil ingestion rates and factors, and consideration of consumer and material specific defaults useful for consumer exposure modeling.

C) OPPT routinely reviews over 1,000 new chemicals in a given year. The vast majority of these chemicals, with some exceptions such as Significant New Use Notices, have never been made. Therefore, there is no existing environmental or biological monitoring data available. However, over the years analytical chemists who frequently analyze environmental samples note commonly encountered analytes. In addition, monitoring studies reported in the literature tend to focus on a known group of chemicals. While there is a larger effort to characterize unknown chemicals, this effort is focused on defining known chemicals that have been detected in the environment or biota. The contractor shall conduct two interviews with analytical chemists at EPA or other authoritative U.S. government bodies who collect monitoring data to compile a list of chemicals which have been commonly found in different media. The contractor shall also conduct a targeted literature search to identify the media, confirm presence/absence, and the sampling location. The contractor shall work closely with EPA to develop interview questions and literature search criteria and will begin work upon receipt of technical direction. EPA will provide a list of chemicals and supporting information as a starting point. The final deliverable will be a streamlined database (Excel or Access) with CAS number, chemical name/category, presence/absence in media a-f, sampling location, and data source.

V. QA Requirements: A Quality Assurance Project Plan (QAPP) is required. A Quality Assurance Project Plan documents the planning, implementation, and assessment procedures for a particular project, as well as any specific quality assurance and quality control activities. It integrates all the technical and quality aspects of the project in order to provide a "blueprint" for obtaining the type and quality of environmental data and information needed for a specific decision or use. All work performed or funded by EPA that involves the acquisition of environmental data must have an approved Quality Assurance Project Plan. Details for developing a QAPP can be found at: http://www.epa.gov/QUALITY/qapps.html and the contractor shall be responsible for the development and revisions to the QAPP. Confidential Business Information (CBI) does apply as some of the chemicals may be CBI. An updated QAPP is requested as part of this follow-on work assignment.

VI. Deliverables:

The contractor shall adhere to the following schedule:

Task	Deliverable	Delivery Schedule
Task	**Deliverable**	**Delivery Schedule**
1	Work Plan	20 days after effective date of WA
1	QAPP	Within 1 month of expiration of previously accepted QAPPs (January 2017)
2	Final version of CEM	December 31, 2016
3	Exposure Assessment Work	As required by technical direction, generally within 3 months of effective TD.
3	Exposure Assessment Support	As required by technical direction, generally within 1-3 weeks of effective TD.
4	Lab Report including data	June 30, 2016
5	SPF model (name TBD)	April 31, 2016
6	A- Exposure Protocols B- Exposure Factors/Activity Patterns C- Monitoring Database	Within 3 weeks of Technical Direction Within 2 weeks of Technical Direction Within 2 months of Technical Direction

VII. Reporting Requirements:

The contractor shall provide monthly progress reports in accordance with the terms of the contract. In addition, the EPA WAM is requiring weekly reporting of LOE and dollars consumed by sub-task (per week and cumulative). This hour and dollar tracking report should be sent bi-weekly via e-mail to the WAMs and Project Officer (PO). It shall be in the form of an Excel spreadsheet unless otherwise specified by the WAM. Each week, the contractor shall input the LOE and dollars used into new columns and/or rows for each sub-task while retaining the data from previous weeks. This will allow the EPA WAM and PO the ability to track all of the sub-tasks for this work assignment throughout the performance period. The contractor shall initiate a weekly call on project progress and shall identify issues or questions at that time. The contractor shall prepare summary notes describing each meeting's topics, action items, and decisions; the contractor shall circulate the summary to the attendees within one business day of the meeting. The contractor shall submit work products in electronic as well as hard copy form. In addition, the contractor shall deliver to the WAM each draft and final report in electronic format that is readable by windows-based word-processing (Microsoft Word 2007), graphics (Microsoft PowerPoint 2007), spreadsheet (Excel 2007), and database (Access 2007) programs. The contractor shall also provide electronic copies of reports in PDF format. All spreadsheet and/or database shall be documented and include information such as:

Prepare and include an Intro (read me) tab with the following information:

- General heading: The scope of the spreadsheet/database e.g., "Literature Search of Phthalates Exposure/Monitoring Data" X CAS numbers – provided by EPA and contained in the first column of tab "a".
- The search strategy used including search engines searched.
- A date or period, e.g., Sept. 2012 or Sept-Oct. 2012, that data sources were collected, that the spreadsheet was originally submitted (generate a version number and insert here and on the file name). Future data inputs would include a new date and version number, and new file name. A description of what the changes included would be provided, e.g., "*inclusion of 11 data sources in tab A and included in tab X summary statistics".*
- The QA/QC process used to collect the data and for minimizing data entry or interpretation errors, etc.
- A key for all column headings including units spelled out.
- A description of each sheet (e.g., *summary statistics page - concentrations of water and soil data with mean, median, and range calculated excluding concentrations that are blank or marked 'NA'*) or related spreadsheet, if separate.